K070888

SECTION 2: 510K SUMMARY

JUL - 3 2008

Date of application: March 2007
Applicant's name: CEC Electronica S.R.L.
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Product Information

Common name: Powered Muscle Stimulator
Trade name: COMBI 8 MAX
Product Codes: IPF, GZJ and LIH
Regulation Numbers and Descriptions:
890.5850 - Powered muscle stimulator (IPF)
882.5890 - Transcutaneous electrical nerve stimulator for pain relief (GZJ)
Interferential Current Therapy (LIH - Pre-Amendment, unclassified)
Panel Code: 89
Classification Advisory Committee: Physical Medicine
Establishment Registration Number: to be assigned

Information on devices to which substantial equivalence is claimed:

510K #	Trade or propriety name	Manufacturer	Class
K984114	SYS STYM 294	Mettler Electronics Corp.	II
K062354	Vectra Genisys	Chattanooga Group	II
K960969	Galva 5-T	Zimmer Elektromedizin Gmbh	II

Technological characteristics, for each output mode, were provided and compared to the predicate devices, in compliance with the guidelines included in FDA Guidance Document for Powered Muscle Stimulator 510(k)s.

Device Definition

The COMBI family by CEC, is a line of multi-wave pulse generators, intended for medical purposes.

The COMBI generators are capable of producing different wave types, such as: three Russian currents (1:1, 2:1, 4:1), symmetric TENS, and symmetric in burst mode: asymmetric TENS, and asymmetric in burst mode; bipolar interferential; three types of impulses, rectangular, triangular, exp + direct current.

The devices deliver the predetermined electrical pulses through skin contact adhesive electrodes, connected to up to four or eight independent body channels, depending on the specific model. (The prefixes 4 and 8 designate the number of channels, respectively).

Three different configurations of Multiwave Generator devices comprise the COMBI product line:

1. COMBI Digital
2. COMBI Trend
3. COMBI Max

The following table gives a summary of the waveforms featured by each one of the three device configurations:

	Russian 1:1	Russian 1:1, 2:1 ,4:1	TENS sym. & asym.	Tetrapolar Interferential	Bipolar Interferential	Rect. & Square Impulses	Direct Current
COMBI Digital	✓						✓
CMBI Max		✓	✓			✓	✓
COMBI Trend		✓		✓	✓		

For more details regarding the device physical and performance sharacteristics please refer to Section 4 of the submission.

Intended Use

Depending on device model, and the specific waveform applied – COMBI pulse generators are indicated for the following uses:

COMBI 4/8 DIGITAL, COMBI TREND 4/8

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous
- thrombosis
- Maintaining or increasing range of motion.

COMBI 4/8 MAX

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion.

For TENS waveform:

- Relief of chronic, intractable pain
- Adjunctive treatment of post surgical or post traumatic acute pain

Declaration of Conformity

The COMBI 8 MAX device is in compliance with the following FDA recognized standard:

✓ IEC 60601-2-10 (1987-12) Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators

A full statement of Declaration of Conformity to recognized standards is included in the submission.

Summary

The attached documents contain the information required in accordance with FDA regulations at 21 C.F.R. Part 807.87. As indicated above, throughout the submission preparation the Guidance document for Powered Muscle Stimulator 510(K)'s was used to address the risks associated with the device.

In particular, the Technological Characteristics were written according the attachment II of the guidance, the Instructions for Use were written by taking into consideration all the precautions and contraindications that appear in the guidance. The device labeling was prepared according the attachment II- Labeling guidance. The standard indication for use for powered muscle stimulators was adopted from the guidance. The software validation was performed by using the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The COMBI product line, subject of this submission, constitutes a safe, reliable and effective medical device meeting all the declared requirements of its intended use. The device presents no adverse health effect or safety risks to patients when used as intended.

We trust that the information provided in this SE file will be sufficient to enable FDA to find the COMBI product line substantially equivalent to the predicate devices as:

- ✓ The intended use is identical to that of the cleared predicate device.
- ✓ The fundamental scientific technology is identical to that of the cleared predicate device.
- ✓ The modification relative to the cleared predicate device does not introduce any new hazards and does not affect the mitigations and CAPA. These modifications as compared with the predicate device are described in detail in the Substantial Equivalence to Cleared Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CEC Electronica S.R.L.
% Mr. Benny Arazy
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Israel

JUL - 3 2008

Re: K070888
Trade/Device Name: Combi 8 Max
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, LIH
Dated: June 19, 2008
Received: June 26, 2008

Dear Mr. Arazy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3: INDICATIONS FOR USE

510(k) Number: K070888

Device Name: COMBI 8 MAX

Indication for Use:

Depending on device model, and the specific waveform applied – COMBI pulse generators are indicated for the following uses:

COMBI 4/8 DIGITAL, COMBI TREND 4/8

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous
- thrombosis
- Maintaining or increasing range of motion.

COMBI 4/8 MAX

- Relaxation of muscle spasms
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For TENS waveform:

- Relief of chronic, intractable pain
- Adjunctive treatment of post surgical or post traumatic acute pain

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-The-Counter Use ☐

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070888